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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PATRICK THEODOOR CHRISTIAN VAN DEN BOGAARD and ASTRID ELISABETH VISSER.[1]

Appeal 2016-003313
Application 13/262,844
Technology Center 1600

Before DONALD G. ADAMS, JOHN E. SCHNEIDER, and RYAN H. FLAX, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for detecting *Clostridium difficile* which have been rejected as not being directed to patentable subject matter and as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] Appellants identify the Real Party in Interest as KONINKLIJKE PHILIPS ELECTRONICS NV. Appeal Br. 3.

STATEMENT OF THE CASE

The present invention is directed to a method for detecting and characterizing a toxinogenic strain of *Clostridium difficile*. Spec. 1.

Claims 1, 3–10, 13, and 14 are on appeal. We find Claim 1 is representative (the remaining claims fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv)); it reads as follows:

> 1. A method for the detection and characterization of a toxinogenic *Clostridium difficile* strain in a sample, comprising the following steps:
>
> a. providing a sample; and
>
> b. performing a multiplex PCR assay in an amplification cartridge, comprising the steps of,
>
> i. analyzing the sample with respect to the presence or absence of the cytotoxin tcdB gene; and
>
> ii. analyzing the sample with respect to the presence or absence of one or more of the following deletions in the tcdC gene,
>
> a) an 18 bp deletion in SEQ ID NO: 1 from nucleotide 330 to nucleotide 347;
> b) a 36 bp deletion in SEQ ID NO: 1 from nucleotide 301 to nucleotide 336;
> c) a 39 bp deletion in SEQ ID NO: 1 from nucleotide 341 to nucleotide 370;
> d) a 54 bp deletion in SEQ ID NO: 1 from nucleotide 313 to nucleotide 366;
> e) a single nucleotide deletion at position 117 of SEQ ID NO: 1; and
>
> iii. analyzing the sample with respect to the presence or absence of the enterotoxin tcdA gene 1.8 kb deletion,
>
> wherein if the tcdB gene sequence is present, the tcdA deletion is absent, neither the single nucleotide deletion at position 117 of SEQ ID NO: 1 is present, nor the 18 bp deletion is present, nor the 39 bp deletion is present, then the sample is scored as toxinogenic *Clostridium difficile*.

The claims have been rejected as follows:

Claims 1, 3–10, 13, and 14 stand rejected under 35 U.S.C. § 101 as not being directed to patentable subject matter.

Claims 1, 3–10, 13, and 14 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Persson[2] in view of Antikainen[3] and Fuernkranz.[4]

THE REJECTION UNDER 35 U.S.C. § 101

Issue

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that the rejected claims recite subject matter ineligible for patenting under 35 U.S.C. § 101.

35 U.S.C. § 101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

The Supreme Court has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and

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[2] Persson et al., *New Multiplex PCR Method for the Detection of Clostridium difficile Toxin A (tcdA) and Toxin B (tcdB) and the Binary Toxin (cdta/cdtB) Genes Applied to a Danish Strain Collection,* 14 CLINICAL MICROBIO. INFECT. 1057–64 (2008) ("Persson").

[3] Antikainen et al., *Detection of Virulence Genes of Clostridium difficile by Multiplex PCR,* 117 APMIS 607–613 (2009) ("Antikainen").

[4] Fuernkranz et al., US 2007 /0026426 Al, published Feb. 1, 2007 ("Fuernkranz").

abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S.Ct. 2347, 2354 (2014).

The Federal Circuit has summarized the Supreme Court's two-part test for distinguishing between claims to patent-ineligible exceptions, and claims to patent-eligible applications of those exceptions, as follows:

> Step one asks whether the claim is "directed to one of [the] patent-ineligible concepts." [*Alice*, 134 S.Ct. at 2354]. If the answer is no, the inquiry is over: the claim falls within the ambit of § 101. If the answer is yes, the inquiry moves to step two, which asks whether, considered both individually and as an ordered combination, "the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo* [*Collaborative Services v. Prometheus Labs, Inc.*, 132 S.Ct. 1289, 1297 (2012)]).
>
> Step two is described "as a search for an 'inventive concept.'" *Id.* (quoting *Mayo*, 132 S.Ct. at 1294). At step two, more is required than "well-understood, routine, conventional activity already engaged in by the scientific community," which fails to transform the claim into "significantly more than a patent upon the" ineligible concept itself. *Mayo*, 132 S.Ct. at 1298, 1294.

Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (paragraphing added).

We agree with the Examiner that the appealed claims are unpatentable. Indeed, the Federal Circuit's recent decision in *Genetic Techs Ltd. V. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016), compels us to affirm the Examiner's rejection of the claims.

The patent-at-issue in *Genetic Technologies* disclosed methods for detecting a coding region of DNA based on its relationship to non-coding regions. 818 F.3d at 1372–73. The inventor discovered, contrary to prevailing thought, that coding regions (i.e., exons) correlated with non-

coding regions (i.e., introns) within the same gene or elsewhere in the genome. *Id.* at 1372. The inventor claimed that discovery as a "method for detection of at least one coding region allele" that encompassed within its scope "detecting a coding region allele by amplifying and analyzing any linked non-coding region, which could be found within the same gene as the coding region, within a different gene, or within an intergenic region." *Id.* at 1372–73.

Starting with step one of the *Mayo/Alice* test, the Federal Circuit observed that "claim 1 covers a method of detecting a coding region of a person's genome," and that the "product of the method of claim 1 is information about a patient's natural genetic makeup" that "relies on the existence of linkage disequilibrium between the non-coding and coding regions." *Genetic Techs.,* 818 F.3d at 1374–75. The court further observed that "the patent claim focuses on a newly discovered fact about human biology (the linkage of coding and non-coding regions of DNA), involves no creation or alteration of DNA sequences, and does not purport to identify novel detection techniques." *Id.* at 1376. Thus, the court concluded, the claims were directed to a law of nature. *Id.*

Turning to step two, the court "examine[d] the elements of the claim to determine whether it contains an inventive concept sufficient to transform . . . the law of nature into a patent-eligible application." *Id.* at 1376 (citing *Alice,* 134 S. Ct. at 2357 (alternations omitted)). The Court first noted that "a claim directed to a newly discovered law of nature . . . cannot rely on the novelty of that discovery for the inventive concept necessary for patent eligibility; instead, the application must provide something inventive,

beyond mere well-understood, routine, conventional activity." *Id.* The court then analyzed the two claimed method steps—"amplifying" genomic DNA and "analyzing" the amplified DNA—and found that both represented "well known, routine, and conventional" techniques. *Id.* at 1377. Thus, the court concluded, "the physical steps . . . do not, individually or in combination, provide sufficient inventive concept to render claim 1 patent eligible." *Id.*

Appellants admit that the genes and deletions within the genes recited in the claims are natural phenomena. Appeal Br. 7. Appellants contend that the claimed method involves performance of a PCT assay for specific combination of genes or nucleotides that is not taught or suggested by the prior art and that this renders the method patentable. Appeal Br. 8–9. As discussed more fully below, the assay techniques are well known in the art (routine and conventional). Appellants point to nothing in the claims that recites an assay that is different from that used in the art. Thus the invention is directed to a law of nature.

Turning to the second step of the *Alice/Mayo* test, we look at the steps of the method recited in claim 1, which includes performing a multiplex PCR assay in an amplification cartridge. Appeal Br. 18 (CLAIMS APPENDIX). The PCR assay in turn comprises a series of assays to determine the absence or presence of certain genes or nucleotide sequences. *Id.* As the Examiner has demonstrated, the PCR assay is performed using well known, routine and conventional techniques. Ans. 12. We conclude

that the recited steps do not "provide sufficient concept to render clam 1 patent eligible." *Genetic Techs.,* 818 F3d at 1377.

We are not persuaded by Appellants' arguments as to patentability. First, Appellants argue that the claims recite patentable subject matter because the

> analysis is clearly not merely an observation of a natural phenomenon and cannot be "accomplished mentally" as asserted by the Examiner. . . . Instead, a person with ordinary skill in the art would readily recognize that the step of analyzing the sample with respect to the presence of the specific genes or nucleotides involves the performance of specific procedures in the PCR assay in order to detect the presence of such genes or nucleotides.

Appeal Br. 8. While the claims require additional steps, Appellants do not persuade us that those steps add anything to the law of nature beyond routine, conventional activity. Thus the additional steps do not render the claims patent eligible.

Next, Appellants argue that the Examiner failed to sufficiently show that the methods for assaying encompassed by the claim are non-obvious. Appeal Br. 8–9. We disagree. As the Examiner points out,

> The use of a cartridge in multiplex PCR analysis was well-known, routine and conventional in the art at the time the invention was made as evidenced by cited prior art made of record in particularly Fuernkranz et al. which provides a general teaching for the analysis of pathogens, such as bacterial, virus and the like using a portable instrument capable of analyzing

> multiple samples and configures to perform multiplex PCR in at least one pre-filled reagent cartridge (*see e.g.*, para. [0087]).

Ans. 12–13. As discussed more fully below, the only aspect of the invention not taught by the references is the existence of the 1.8kb deletion in the tcdA gene, which Appellants admit is a natural phenomenon. Appeal Br. 7. There can be no serious dispute that the techniques used in the assay were well known in the art before the earliest-effective filing date of the present application. *See Genetic Techs.,* 818 F.3d at 1377 (characterizing PCR and sequencing as "clearly well known, routine, and conventional" in 1989).

Appellants argue that the appealed claims "do not foreclose others from using the natural principle concerning the analysis of the presence of the specifically selected genes and nucleotides from future innovation" which supports a finding that the subject matter is patent eligible. Appeal Br. 9.

We are unpersuaded. The Federal Circuit has expressly rejected similar contentions regarding preemption, stating that a patentee's "attempt to limit the breadth of the claims by showing alternative uses . . . outside of the scope of the claims does not change the conclusion that the claims are directed to patent ineligible subject matter." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015). The court explained that, "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. . . . Where a patent's claims are deemed only to disclose patent ineligible subject

matter under the *Mayo* framework . . . preemption concerns are fully addressed and made moot." *Id.*

In the present case, as discussed above, Appellants' claim 1 is limited to patented ineligible subject matter under the *Mayo* framework. Thus, that alternatives outside the claims are not preempted does not demonstrate patent eligibility.

We conclude that the Examiner has established by a preponderance of the evidence that the rejected claims recite subject matter ineligible for patenting under 35 U.S.C. § 101.

THE REJECTION UNDER 35 U.S.C. § 103(a)

Issue

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that the rejected claims would have been obvious over Persson combined with Antikainen and Fuernkranz under 35 U.S.C. § 103(a).

The Examiner finds that both Persson and Antikainen teach a method for performing multiplex PCR assays to detect *Clostridium difficile* strains. Final Act. 8. The Examiner finds that Persson teaches the detection of an 18 base pair deletion, a 39 base pair deletion and a 54 base pair deletion in the tcdC gene. *Id.* The Examiner finds that both Persson and Antikainen teach a single deletion at position 117 of the TCDC gene. *Id.* The Examiner finds that both Persson and Antikainen teach the detection of tcdA and tcdB genes. *Id.* The Examiner also finds that Fuernkranz teaches performance of

multiplex PCR in an amplification cartridge. Final Act. 9. The Examiner concluded that

> [o]ne of ordinary skill in the art at the time of the claimed invention would have been motivated to perform the multiplex PCR analysis method of *Clostridium difficile* strains as taught by Persson et al and Antikainen et al in an amplification cartridge as taught by Fuernkranz et al for the obvious benefit of providing a portable and convenient means of performing analysis of multiplex PCR for pathogenic detection as suggested by Fuernkranz et al. The use of a cartridge for multiplex amplification is within the ordinary artisan technical grasp as such apparatus would not negatively alter or modify results of detecting pathogens via multiplex PCR. The combination of the cited prior art is *prima facie* obvious in the absence of secondary consideration.

Id.

Appellants contend that the references do not teach the detection of a 1.8 kb deletion in the tcdA gene. Appeal Br. 12–14. Appellants also contend that the references do not teach detection of the additional deletion recited in claims 4 and 13. Appeal Br. 15–16.

We believe that Appellants have the better position. The Examiner has not pointed to any evidence in the record that teaches detection of a 1.8kb deletion in the tcdA gene. A proper § 103 analysis requires "a searching comparison of the claimed invention—including all its limitations—with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

While the Examiner acknowledges that the references do not teach a 1.8 kb deletion in the tcdA gene, the Examiner construes the claim as not requiring each recited deletion be detected. Ans. 17. We are not persuaded. Claim 1 specifically calls for "analyzing the sample with respect to the

presence or absence of the enterotoxin tcdA gene 1.8 kb deletion." Appeal Br. 18 (CLAIMS APP'X). The wherein clause that follows does not render this step optional, but only states the criteria to be used to characterize the strain. Reply Br. 12.

We conclude that the Examiner has not sufficiently established by a preponderance of the evidence that the rejected claims would have been obvious over Persson combined with Antikainen and Fuernkranz under 35 U.S.C. § 103(a).

SUMMARY

We affirm the rejection based on 35 U.S.C. § 101.

We reverse the rejection based on 35 U.S.C. § 103(a).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED